REMARKS/ARGUMENTS

In an Office Action dated May 17, 2004, claims 14-24 were rejected. Claims 1-14 and 25-26 are cancelled. Claims 15-24 remain pending.

Withdrawal of 35 U.S.C. § 103(a)

Applicants thank the Examiner for withdrawal of the rejection of claims 14-24 under 35 U.S.C. § 103(a).

Claim Rejections – 35 U.S.C. § 112, First Paragraph

The Examiner has rejected claims 14-24 as failing to enable one of skill in the art to make and use the claimed invention commensurate in scope with the claims. The Examiner has asserted that the applicants' own data suggest that only carbohydrates having a dimeric sialyl Lewis x moiety demonstrate any significant binding ability.

Applicants respectfully disagree with the Examiner's grounds for rejection and the above statements. The Examiner's reliance solely upon Tables 1 and 2 is misplaced. Tables 1 and 2 demonstrate binding assayed by thin layer chromatography. As one of skill in the art would recognize, the conditions for thin layer chromatography are different than the administration to a human patient as is currently claimed, which will be much more like that in solution. Further, Tables 1 and 2 only measure binding of two strains, CCUG 17875 and 17874 (see pages 25-26 of the specification). While Table 2 apparently indicates that the repetitive sialyl-Lewis x antigen binds with much higher affinity than the sialyl-Lewis x antigen, as demonstrated on page 17, lines 27-34, follow-up experiments using more accurate techniques show that the two molecules bind with similar affinities, $1x10^8$ M^{-1} and $2x10^8$ M^{-1}, respectively. Thus demonstrating that the thin layer chromatography experiments are less relevant than the other experiments performed by the applicants. Furthermore, the applicants have demonstrated that 15% of the 91 Swedish clinical *H. pylori* isolates tested bound to the sialyl-Lewis a antigen (see page 18, lines 29-34). In addition, Figure 4 demonstrates that four strains tested will bind to two additional sialyl-N-acetyl lactosamine

structures with different spacers (3 atoms and 14 atoms, respectively). Thus, applicants' data does not, in fact, demonstrate that only sialyl-Lewis x antigen works as suggested by the Examiner. Applicants' data demonstrates that the carbohydrate structures tested that fall within the scope of the claims, fucosylated sialylated N-acetyl lactosamine carbohydrate structures, do bind to *H. pylori* clinical isolates, which are the most relevant given that the clinical isolates are strains that actually infected a patient.

Furthermore, the specification provides more that adequate support to enable one of skill in the art to make and use the claimed invention commensurate in scope with the claimed invention. The Examiner has asserted that undue experimentation would be required. However, as indicated in *In re Wands*, undue experimentation is evaluated based upon eight factors, including the quantity of experimentation, the amount of direction or guidance provided, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims. In the present application, undue experimentation is not required for one of skill in the art to make and use the invention commensurate in scope with the claims. Application of the *Wands* factors to the claimed invention clearly supports this. The first *Wand* factor is the quantity of experimentation necessary. The quantity of experimentation is not undue. As disclosed in the application, synthesis and testing several clinical isolates for binding are routine methods and therefore not undue experimentation. It is does not matter that it could take a fair amount of work to screen through molecules to find those that have the highest affinities. The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. All of the synthesis and testing is routine in the art.

The second *Wands* factor is the amount of direction or guidance provided. As discussed with regard to the first *Wands* factor, the nature of the experimentation is all routine, so the techniques used need not be disclosed, and yet they are disclosed in actual working examples. Furthermore, as discussed above, the specification discloses multiple working examples of fucosylated sialylated N-acetyl lactosamine carbohydrate structures that bind to *H. pylori*. Thus, there is a fair amount of guidance provided as how to synthesize and test compounds, and there is a

fair amount of guidance demonstrating that fucosylated sialylated N-acetyl lactosamine carbohydrate structures as are currently claimed are functional in the claimed methods.

The third *Wands* factor is the present or absence of working examples. Applicants have taught actual working examples of the fucosylated sialylated N-acetyl lactosamine carbohydrate structure. As discussed above, the specification demonstrates that sialyl-Lewis x antigen, repetitive sialyl-Lewis x antigen, sialyl-Lewis a antigen, and two additional sialyl-N-acetyl lactosamine structures with different spaces (3 atoms and 14 atoms, respectively) are all capable of binding to *H. Pylori*.

The fourth *Wands* factor is the nature of the invention. In this case, making and using the invention requires only routine chemical synthesis and molecular biology techniques to make and use the invention as claimed.

The fifth *Wands* factor is the state of the prior art. The state of the art is high. As of the priority date of March 19, 1999, chemical synthesis and molecular biology techniques were well worked out and included a high degree of automation for high throughput screening if required. Thus, one of skill in the art is capable of screening through large numbers of fucosylated sialylated N-acetyl lactosamine carbohydrate structures if required; however, as discussed above most likely all the fucosylated sialylated N-acetyl lactosamine carbohydrate will demonstrate some degree of binding to at least a portion of the clinically relevant isolates of *H. pylori*, so such screening would likely only be needed to identify those with the highest affinity.

The sixth *Wands* factor is the relative skill of those in the art. The skill in the art is quite high. Chemical synthesis and screening is done by graduate level research scientists or higher. Such research scientists are well versed in chemical synthesis, molecular biology and screening techniques required by the claimed invention.

The seventh *Wands* factor is the predictability or unpredictability of the art. While the affinity of each and every fucosylated sialylated N-acetyl lactosamine carbohydrate structure for each clinical isolate of *H. pylori* cannot be predicted with one hundred percent accuracy, the working examples provide some degree of predictability that will provide one of skill in the art a starting point. Furthermore, as discussed above, it is likely that most if not all fucosylated sialylated

N-acetyl lactosamine carbohydrate structures will bind to a portion of the clinically relevant isolates of *H. pylori*.

The eighth *Wands* factor is the breadth of the claims. The claims are not unduly broad given that the carbohydrate structures must be both fucosylated ***and*** sialylated N-acetyl lactosamine carbohydrates. Therefore the breadth of the claims is not unduly broad.

Thus given that most if not all of the Wands factors weigh in the favor of the applicants, the invention as claimed would not require undue experimentation by one of skill in the art to make and use the invention commensurate with the scope of the invention. Claim 14 is canceled. Applicants respectfully request that the Examiner withdraw the rejection of claims 15-24 based upon 35 U.S.C. § 112, first paragraph.

CONCLUSION

In light of the above, applicants submit that the pending claims are in condition for allowance. Should there be any remaining issues that remain unresolved; the Examiner is encouraged to contact the undersigned by telephone.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 514862000100. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: August 17, 2004

Respectfully submitted,

By _____

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